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BioCardia Inc. (BCDA-NASDAQ)

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BUY: Building a Unique Cell Therapy Product and Company, “A Tale of Two Products” Allo & Auto

BioCardia announced additional data around its allogenic neurokinin 1 receptor positive mesenchymal stem cell (NK1R+ MSC) program (CardiALLO) for heart failure, and as a possible therapy in COVID-ARDS. What we see is the continued development of a unique cell therapy allo product, “a brand” in what may become a competitive field in regenerative medicine, and a special company which has both an auto and an allo product.

Investment Highlights

Heart Disease – Treating the Underlying Issue. BioCardia strongly believes that stem cells have the power to change the course of cardiovascular disease. This may occur as a result of the trophic effects of these cells when administered directly into the local environment (heart muscle). The cells act like micro-drug factories secreting factors that help to reduce inflammation, reduce scarring, and promote micro-angiogenesis (formation of new blood supply to the tissue). In doing such, it is hoped in the case of an acute ischemic event that the cells can help limit the initial damage and, in the case of chronic disease, may help to arrest the damage, even reverse it partially.

Autologous vs. Allogeneic: BioCardia is developing treatment using both autologous and allogeneic cells. BioCardia developed a diagnostic assay to determine which treatment is best suited for each patient. Autologous stem cell therapy is the company’s leading product, CardiAMP, which is currently in a pivotal Phase 3 trial. Through CardiAMP, the patient’s own bone marrow is extracted and is directly administered to the patient’s heart to allow the most efficacy. If a patient’s CD34 cell count does not reach the requirement for CardiAMP, BioCardia can offer CardiALLO. CardiALLO stands out as an allogeneic stem cell therapy that is based on donated marrow. CardiALLO is designed to be a fast follower behind CardiAMP.

What’s New? As the company plans its next generation of cell therapy, it’s building the science to develop a differentiated allogeneic product (marrow-based cells), in CardiALLO. The specific MSCs used in BioCardia’s allogeneic cell therapy are expanded from cells selected for the presence of the NK1 receptor, which is known to bind to substance P, an important neuropeptide associated with inflammation throughout the body and a primary mediator of inflammation in the airways. Preclinical data (N=26 animals), were treated with both low dose and high dose NK1R+ MSC, echocardiographic measures of cardiac ejection fraction, fractional shortening and cardiac outflow were meaningfully improved, with all three measures being statistically significant for both dosage levels over control animals. An FDA submission for the first indication (CHF) should be IND ready in Q2-20. The company is also evaluating the product’s utility in COVID-ARDS. The animal studies are currently being analyzed, including histology and pathology of the heart and lungs.

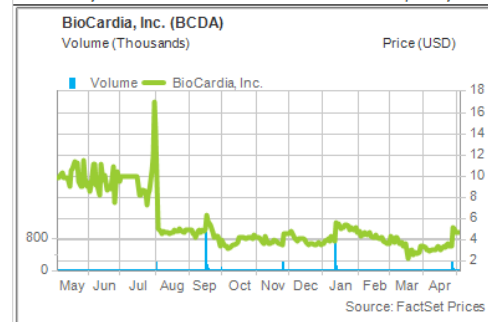
Risks: Partnership risks, Commercialization risks, Financial risks, Clinical and regulatory risks, and Legal and intellectual property risk.

Current Price \$4.86
Price Target \$24.00

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 15,192	\$ 15,568	\$ 16,346
1Q March	\$ 3,903	\$ 3,653	\$ 3,835
2Q June	\$ 3,848	\$ 3,812	\$ 4,002
3Q September	\$ 3,421	\$ 3,972	\$ 4,171
4Q December	\$ 4,020	\$ 4,131	\$ 4,338
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (2.13)	\$ (0.75)	\$ (0.36)
1Q March	\$ (0.08)	\$ (0.32)	\$ (0.10)
2Q June	\$ (0.77)	\$ (0.14)	\$ (0.08)
3Q September	\$ (0.63)	\$ (0.15)	\$ (0.09)
4Q December	\$ (0.65)	\$ (0.15)	\$ (0.09)

EBITDA/Share	(\$0.96)	(\$0.67)	(\$0.36)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data			
52-Week Range	\$2.10	-	\$17.50
Shares Outstanding (mil.)	6.8		
Market Capitalization (mil.)	\$33		
Enterprise Value (mil.)	\$33		
Debt to Capital	0%		
Book Value/Share	\$2.62		
Price/Book	1.9		
Average Three Months Trading Volume (K)	18		
Insider Ownership	35.1%		
Institutional Ownership	3.1%		
Short interest (mil.)	0.3%		
Dividend / Yield	\$0.00/0.0%		



Delivery Matters. One of the characteristics that differentiates BioCardia from competitors in the field is the way the cells are delivered. The cells are administered directly to the patient's heart through the use of their Helix Biotherapeutic Delivery System and the Morph steerable guide. The end result is that more cells stay where they are needed versus other systems where the majority of cells are washed away in the dynamic blood flow associated with the heart. **See Exhibit 5. Cell Quality Matters Too.** BioCardia is talking more and more about its potency assay and the ability to determine in advance of therapy that cells are consistent and viable with its requirements. **See Exhibit 8.**

Roughly \$20B is spent per year for hospitalization costs. Following an operation done on a patient's heart, on average, they are in the hospital for three to four nights spending at least \$10,000 a night. CardiAMP can allow the patient to be released the same day with anticipated savings for the system of up to \$40,000 of unwanted hospital costs. Cell Therapy represents the ability to intervene in heart failure outside of treatment paradigms that exist today. **See Exhibit 2.**

BioCardia is Assisted. The company is conducting numerous clinical trials in heart disease and specifically heart ischemia. Focusing on heart failure consumes a significant amount of a company's resources. BioCardia gets an extra hand as the Centers for Medicare & Medicaid Services (CMS) has funded the ongoing Phase 3 trial of CardiAMP cell therapy system in ischemic heart failure.

Autologous vs. Allogeneic: BioCardia is developing treatment using both autologous and allogeneic cells. BioCardia developed a diagnostic assay to determine which treatment is best suited for each patient. Autologous stem cell therapy is the company's leading product, CardiAMP, which is currently in a pivotal Phase 3 trial. Through CardiAMP, the patient's own bone marrow is extracted and is directly administered to the patient's heart to allow the most efficacy. If a patient's CD34 cell count does not reach the requirement for CardiAMP, BioCardia can offer CardiALLO. CardiALLO stands out as an allogeneic stem cell therapy that is based on donated marrow. CardiALLO is designed to be a fast follower behind CardiAMP.

Phase 3 Update: DSMB Say's No Safety Issues – Recommends that the trial should continue: BioCardia announced that the independent Data Safety Monitoring board (DSMB) has completed its prespecified data review for the Phase 3 pivotal CardiAMP Heart Failure Trial, which included safety follow-up results on 35 patients and all additional data available on the 50 patients randomized in the trial as of the end of August. The DSMB indicated there were no safety concerns with the CardiAMP study results and recommended that the trial continue, as planned. The trial is an ongoing multi-center, double-blinded, randomized (3:2), sham-controlled pivotal CardiAMP Heart Failure Trial that is expected to enroll 260 patients at up to 40 centers nationwide. The trial's primary efficacy endpoint is Six Minute Walk distance at 12 months' post-treatment, a measure of a patient's exercise capacity, and incorporates the impact of MACE and other clinically meaningful events. Secondary efficacy endpoints include quality of life as measured by the Minnesota Heart Failure Quality of Life self-assessment, and superiority relative to MACE and survival.

Finances: As of the last reported quarter (9.2019) the company had \$9 million. BioCardia filed an S1 to raise additional capital.

Valuation: Our product models run out to the year 2030. For CardiAMP and CardiALLO and all the related cardiac indications, each of which represent blockbuster markets, we haircut the revenues by 70% (assume only a 30% probability of success). In addition, in our free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models we apply a risk rate (r) of 30% on-top of the 90% risk cut in our models. Our share count is projected for 2030 and assumes multiple raises. Our models are then equal weighted, averaged and rounded to the nearest whole number to derive our 12 months price target of \$24.00. **See the Valuation section in this report for some comparable valuations and recent transactions.**

Exhibit 1. We view BioCardia as a unique company in the world of stem cells as the company has “The Best of Both Worlds”, that is an Autologous and an Allogenic approach. A patient assay can determine if a patient’s own cells are viable to treat disease and select which therapy is best for each individual patient.

CardiAMP cell therapy system

- Regulated and manufactured as a device based procedure kit with anticipated low cost of goods and long shelf life
- For both leading indications, CardiAMP fits into standard interventional cardiology device channels

CardiALLO cell therapy system

- Commercial launch will leverage experience, training, and delivery systems. As an “off the shelf” cryopreserved cell therapy multiple doses per donor will be available. BioCardia has a unique approach which may address donor variability issues and international distribution
- Cardiology sales of these products are synergistic
- Direct sales force in U.S. selling into the cardiac catheterization suite and interventional cardiologist end users at 1200 hospitals in USA
- Co-exclusive partnering with large reference laboratory on cell proprietary potency assays

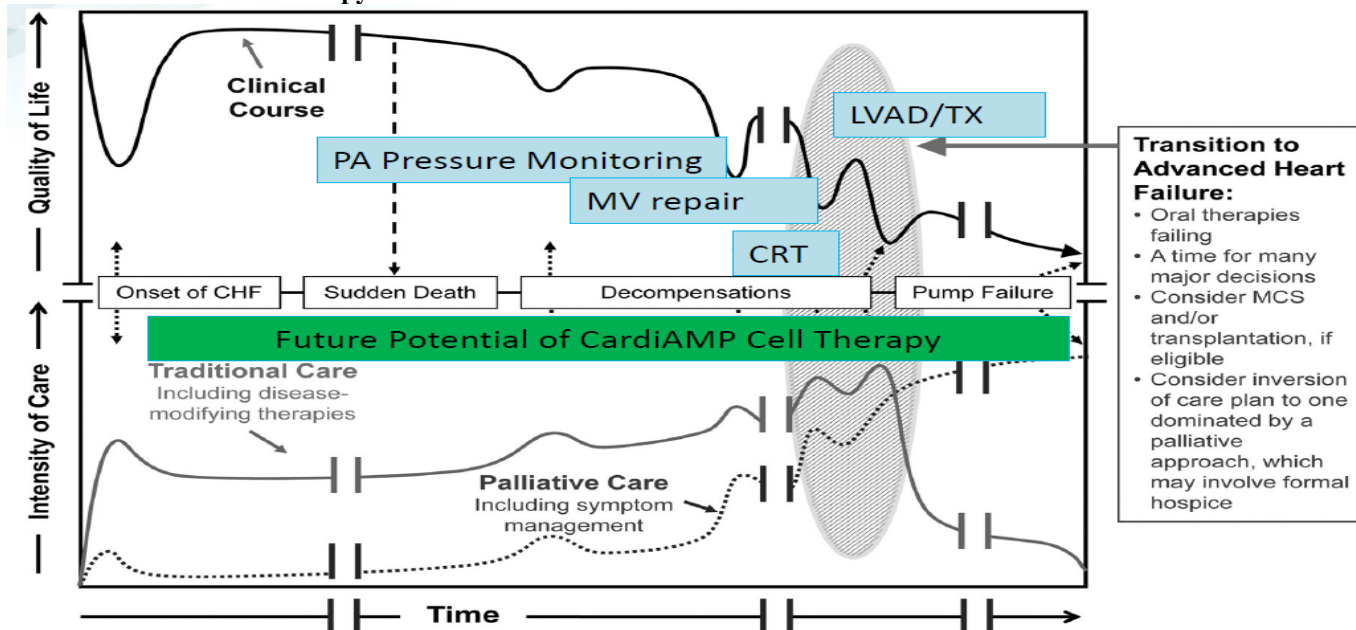


Source: BioCardia July Presentation.

Company Overview

BioCardia is a clinical stage regenerative medicine company developing therapies for cardiovascular diseases. It is well known that the cardiovascular market has large unmet medical needs and BioCardia believes CardiAMP and CardiALLO are part of the solutions for patients following a heart attack and or diagnosed with chronic myocardial ischemic and or ischemic related cardiac disease. The company's lead program, CardiAMP, incorporates a proprietary molecular model in order to determine if a patient's own bone marrow qualifies as a candidate for this therapy. The company hopes with this therapy to improve the quality of life for patients following treatment for heart disease. CardiAMP was designed to be delivered in a 60-90-minute procedure. CardiALLO is an option for those patients who are not able to produce enough viable cells to manufacture CardiAMP. Both heart failure trials, BCDA-01 and BCDA-02 have been supported by CMS (Medicare) which has offset the financial burden for expensive HF trials. The interest in cell-based therapy for heart failure is rising for multiple reasons including the lack of adverse events, high safety profile, and its ability to change the treatment paradigm in cardiovascular disease.

Exhibit 2. Role of Cell Therapy in Clinical Course of Heart Failure



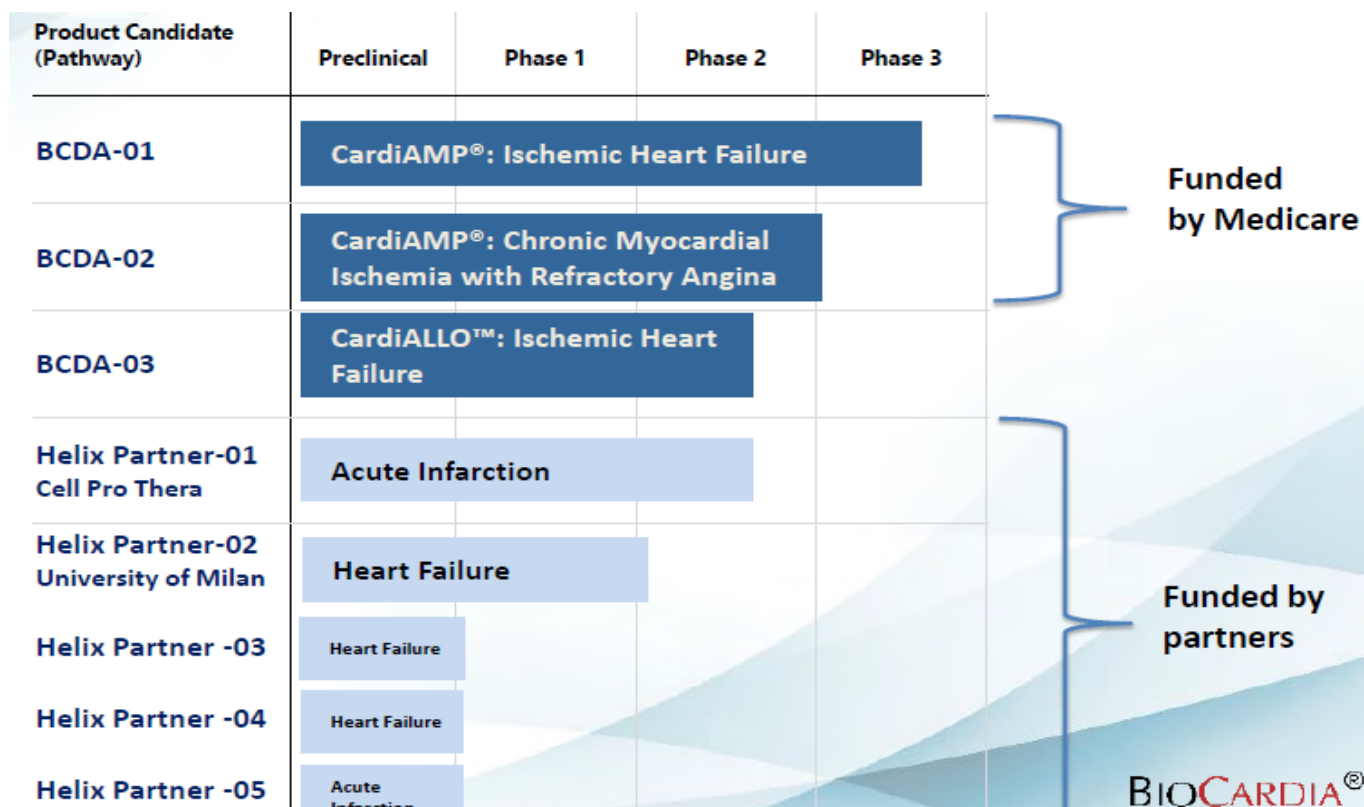
Source: Modified from Decision Making in Advanced Heart Failure, A Scientific Statement From American Heart Association, Circ 2012

Exhibit 3. Upcoming Catalysts for BioCardia

Product	Indication	Event	Timeline	Impact
BCDA-01: CardiAMP Cell Therapy	Ischemic Heart Failure	Complete enrolling pivotal Phase 3 trial	2H20	++
BCDA-01: CardiAMP Cell Therapy	Ischemic Heart Failure	Complete Phase 3 and submit for US and EU approval	3Q21	+++
BCDA-01: CardiAMP Cell Therapy	Ischemic Heart Failure	Approval and Launch	2H22	+++
BCDA-02: CardiAMP Cell Therapy	Chronic Myocardial Ischemia	Complete enrollment for pivotal Phase 3	2H22	++
BCDA-02: CardiAMP Cell Therapy	Chronic Myocardial Ischemia	Complete Phase 3 and submit for US and EU approval	4Q23	+++
BCDA-02: CardiAMP Cell Therapy	Chronic Myocardial Ischemia	Approval and Launch	1Q24	+++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Seek Orphan Status	2021	+
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Phase 1/2 Investigational New Drug approved	4Q19	+
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Begin enrollment of Phase 1/2 Study	3Q20	+
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete enrollment for Phase 1/2 trial	3Q22	++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete study and file for pivotal Phase 3 trial	3Q23	++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Begin enrollment of pivotal Phase 3 trial	4Q23	++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete enrollment of Phase 3 trial	2H25	+++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete Phase 3 and submit for US and EU approval	3Q26	+++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Approval and Launch	1Q27	+++

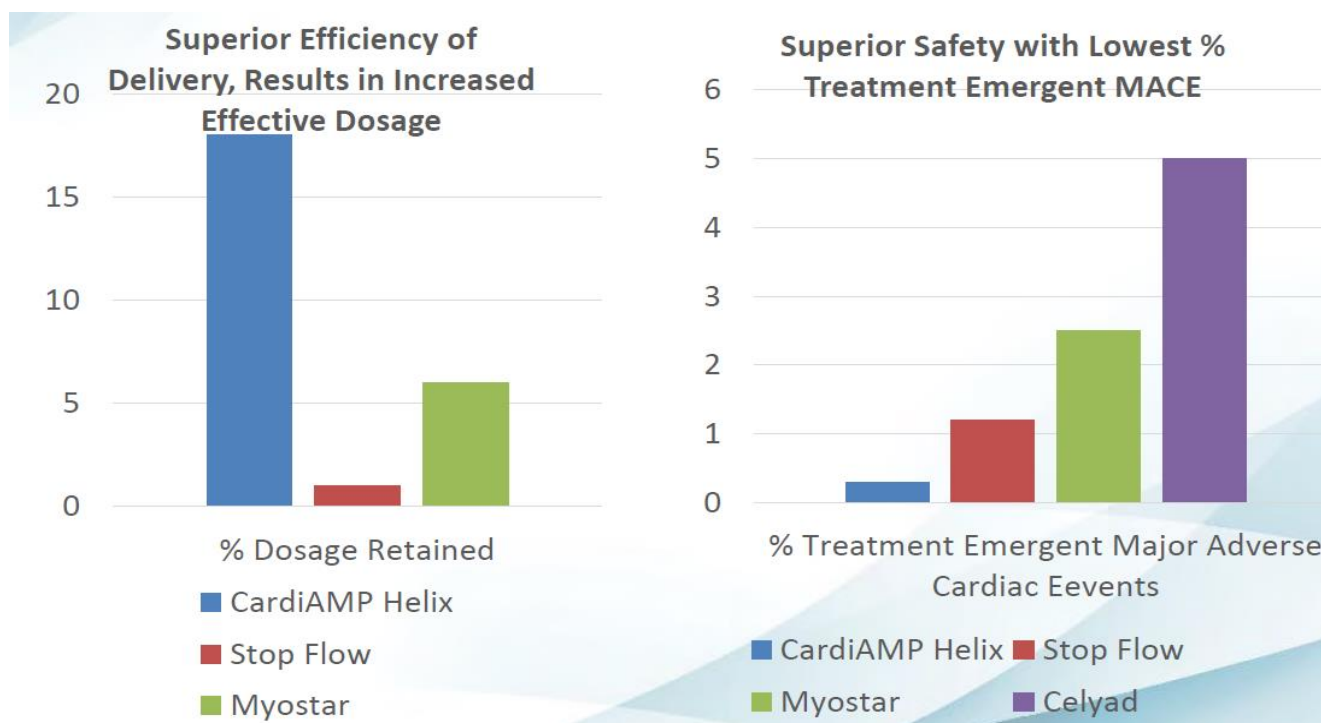
Stock Significance Scale: + of moderate importance; ++ higher level; +++ highly

Exhibit 4. Advanced clinical pipeline



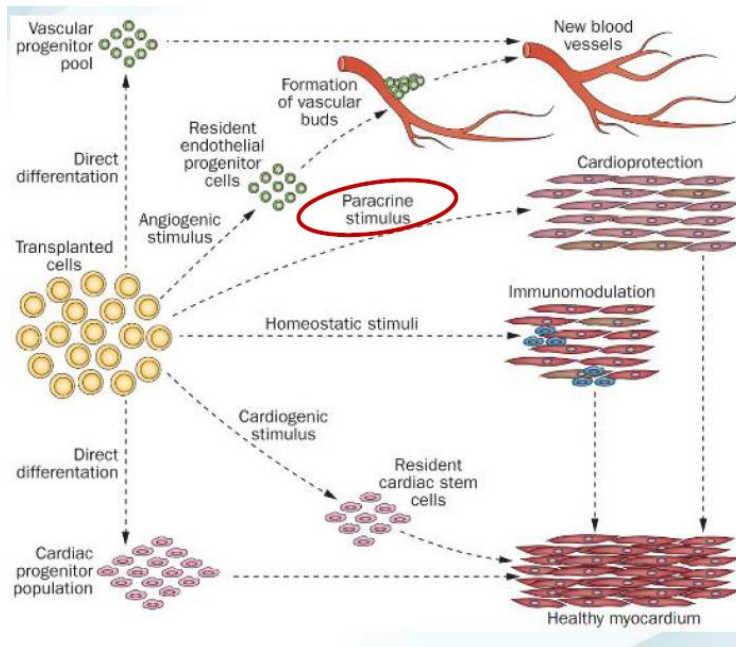
Source: BioCardia Presentation.

Exhibit 5. Performance of CardiAMP Cell Delivery with Proprietary Helix – The Ability to Deliver and Retain Dose on Target



Source: Mitsutake et al, Int.Heart J. (2017), Duckers H et al, Transcatheter Therapeutics 2018.

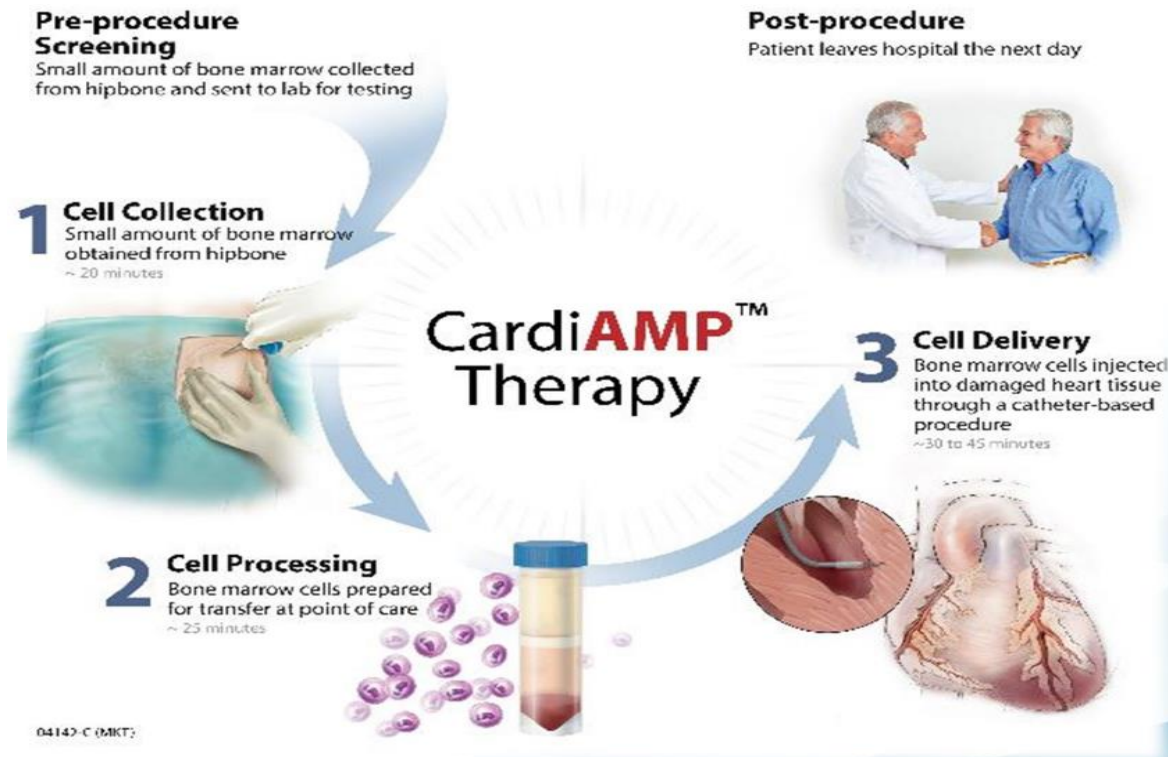
Exhibit 6. Mechanistic basis for regeneration. Transplanted cells are hypothesized to benefit the heart through direct and indirect pathways.



- **Direct Regeneration:** Transplanted cells actively home to injury sites and differentiate into new functional tissue to augment organ function.
- **Indirect Regeneration:** Transplanted cells secrete stimulatory cytokines to instigate an innate regenerative response from resident stem cells.
- **Accelerating a natural process:** Cells from bone marrow home to injury in the heart. Animal work supports reduced fibrotic scar and enhanced micro vessel density. Clinical work supports that there is benefit in this approach.

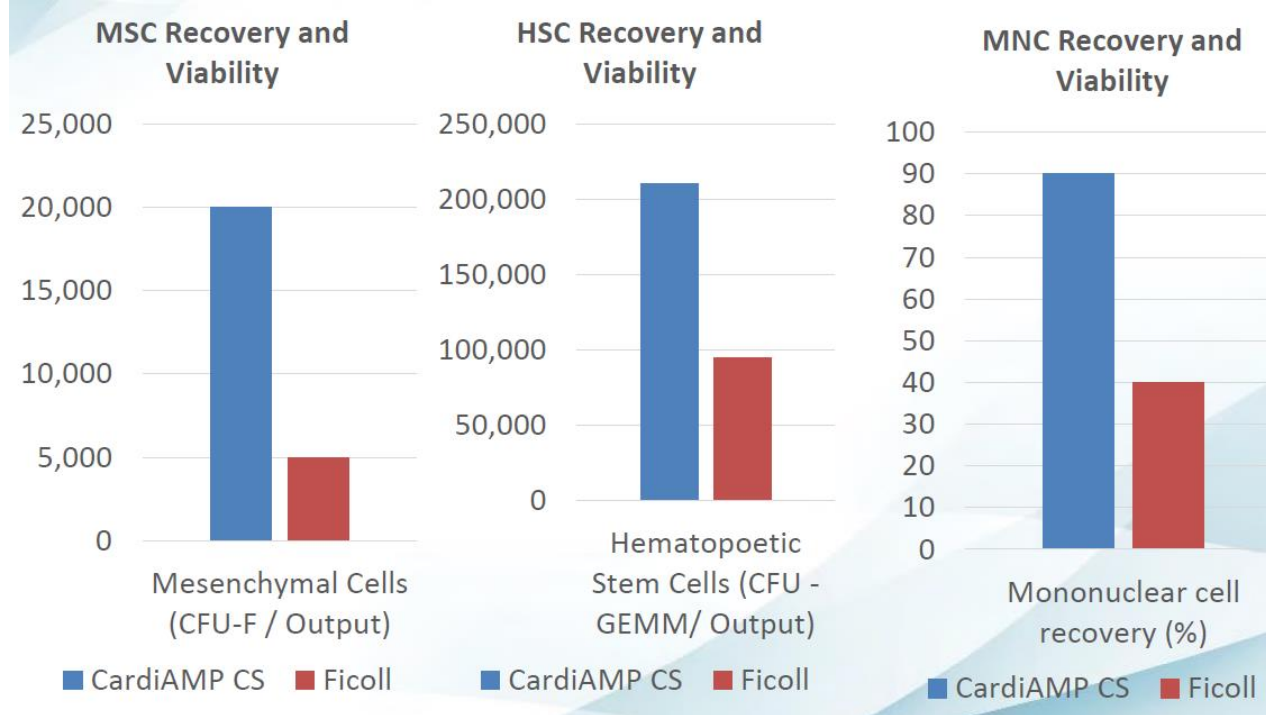
Source: BioCardia July Presentation.

Exhibit 7. Investigational CardiAMP (Autologous Model) cell therapy system, from collection and screening to delivery with a specialized catheter.



Source: BioCardia July Presentation.

Exhibit 8. Potency Assay – Cell Quality Matters



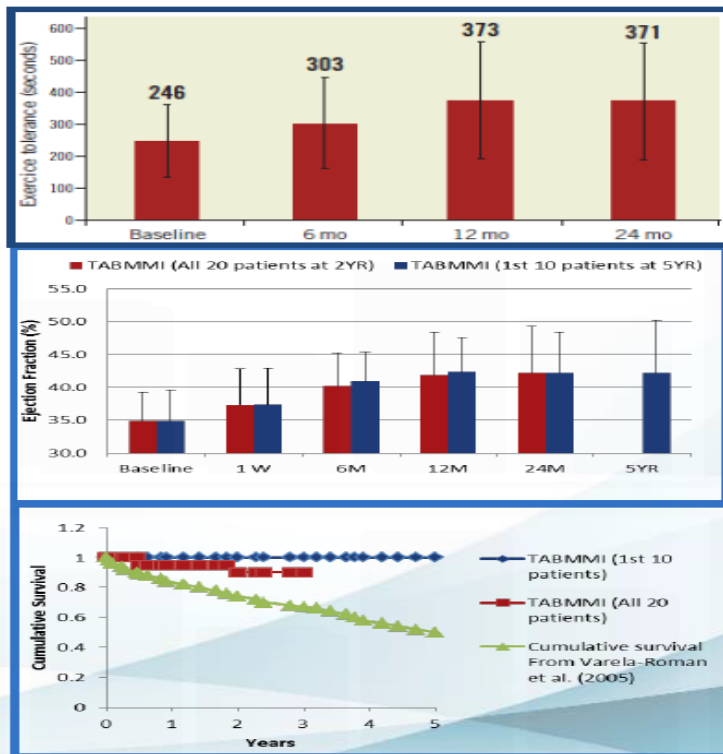
Source: BioResearch Open Access, Volume 4.1, 2015

Exhibit 9. Investigational CardiAMP cell therapy system pre-procedure screening selects patients likely to respond to CardiAMP.



Source: BioCardia July Presentation.

Exhibit 10. On All Key Metrics (used for approval by regulators), CardiAMP has Shown Improvement.



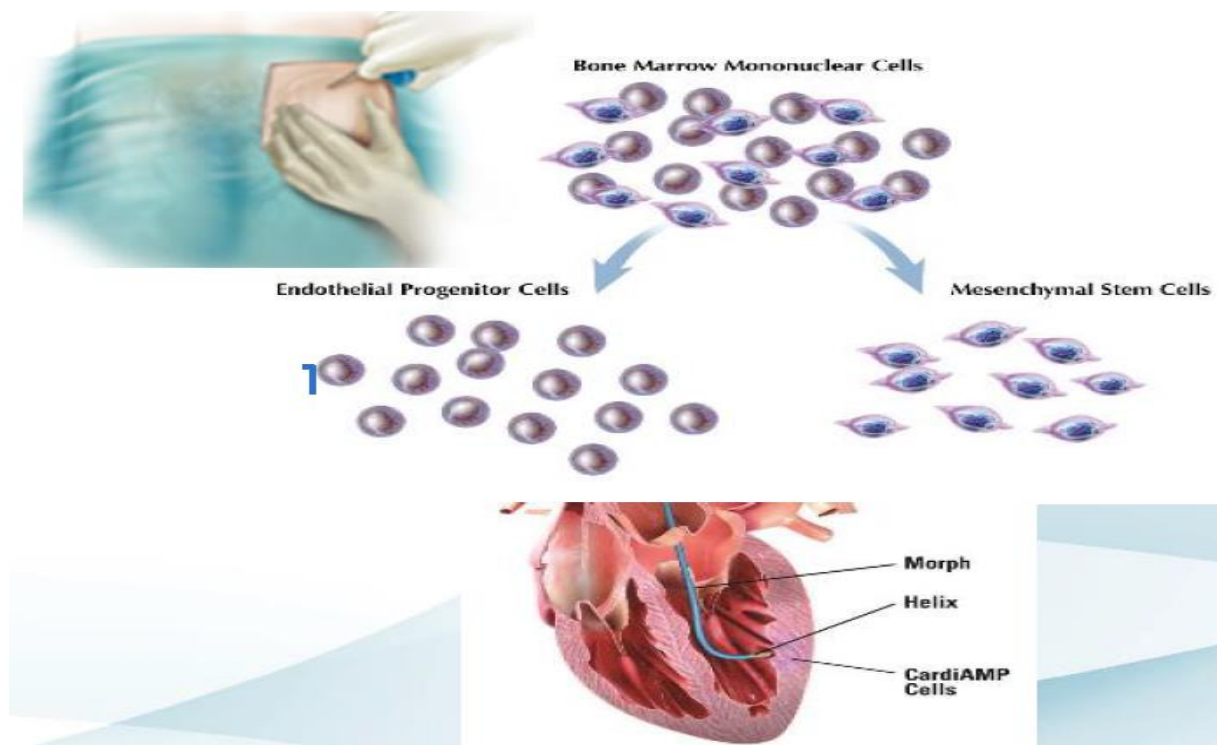
Exercise Tolerance Time
Improvement at 12 & 24M:
~ +125 sec, $p=0.006$

Improved LV Ejection Fraction
Improvement at 12 & 24M:
~ +7 %, $p=0.000006$,
 $p=0.00005$

Improved survival at 3 and 5 year follow-up
1st 10 patients – No death
All 20 patients – 2 deaths:
D177 Elective heart transplant
D695 Unknown causes
BIOCARDIA®

Source: BioCardia July Presentation.

Exhibit 11. Transendocardial Autologous Cells in Heart Failure Trial (TAC-HFT)



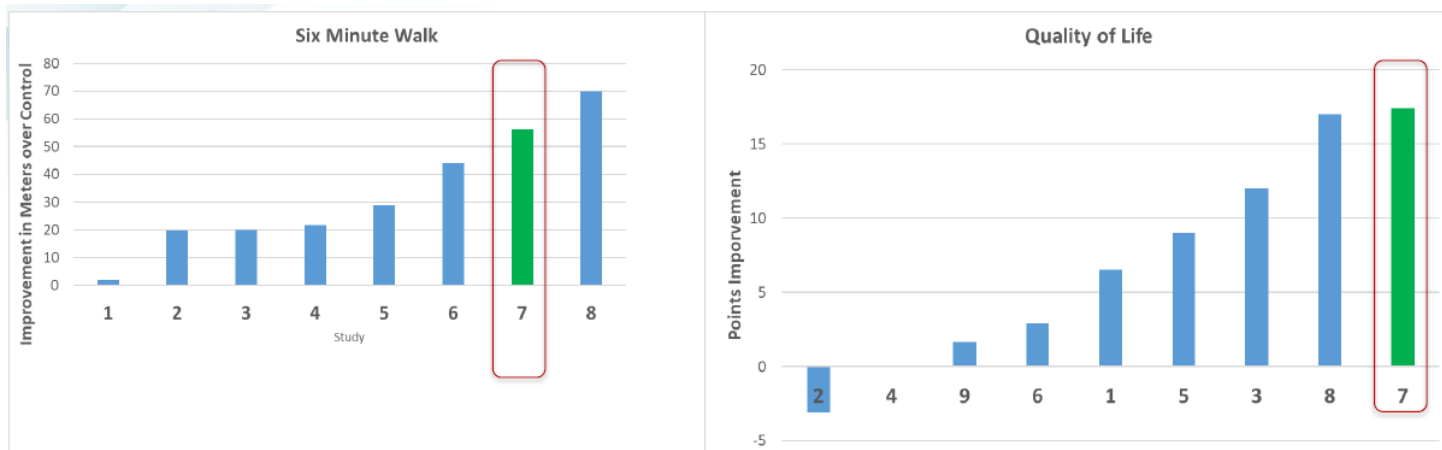
Source: BioCardia July Presentation.

Exhibit 12. Phase 2 Placebo Controlled Randomized Trial Results: Improvement Shown in Key Metrics.

Secondary Efficacy Endpoints	Active (Mean)	Placebo (Mean)	Treat. Difference	Favors CardiAMP Therapy	P-value
6 minute walk (meters) N=28, Mean \pm St Dev	+14.3 \pm 59.6	-42.0 \pm 18.1	+56.3	✓	0.049
MLHF quality of life (pts) N= 29, Mean \pm St Dev	-7.7 \pm 17.8	+9.7 \pm 24.8	-17.4	✓	0.038
Maximum Oxygen Use (mL/kg·min)	+0.16	-0.870	+1.03	✓	0.321 NS*
NY Heart Association Class	-0.42	-0.25	-0.17	✓	0.638 NS
LV End Systolic Volume (ml)	+3.2	+47.2	-44	✓	0.129 NS
LV End Diastolic Volume (ml)	+4.5	+51.2	-46.7	✓	0.149 NS
LV Ejection Fraction (%)	+0.97	-2.38	+3.35	✓	0.252 NS

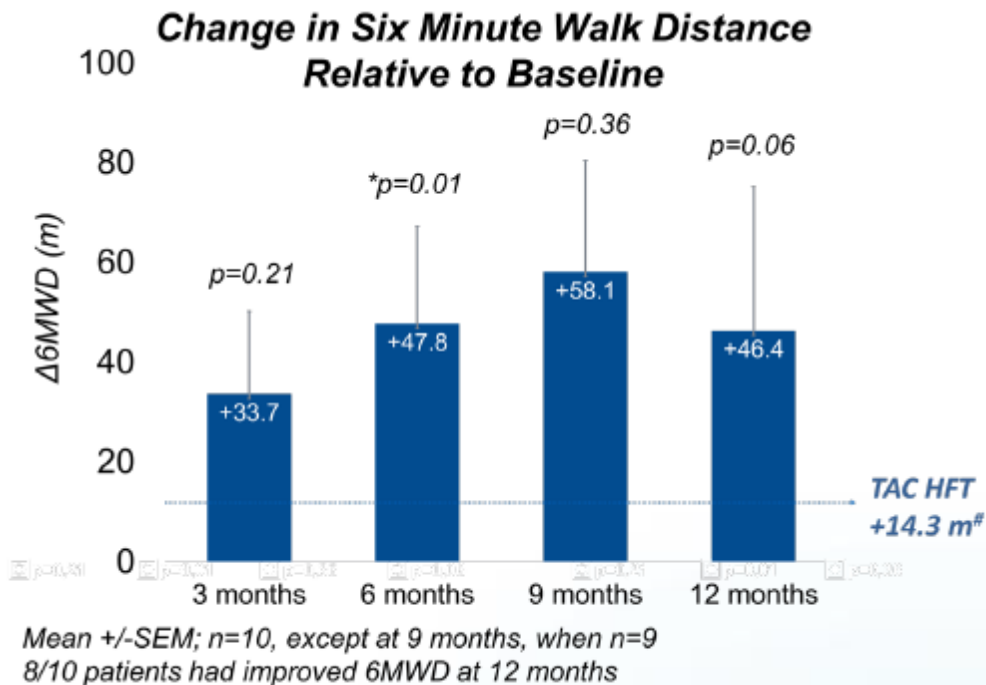
Source: BioCardia July Presentation.

Exhibit 13. Phase 2 Efficacy Results in Six Minute Walk Relative to Other (Entresto) CRT and Heart Failure Therapies.



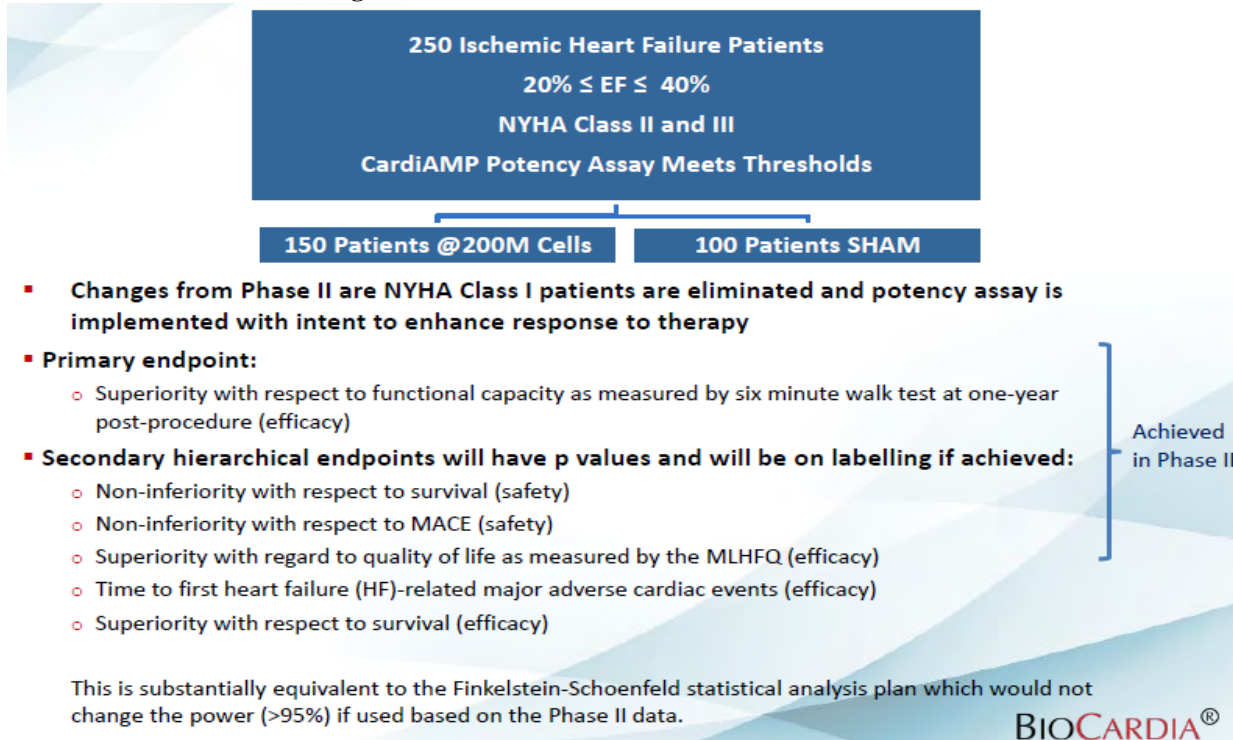
Source: BioCardia July Presentation.

Exhibit 14. Phase 3: Change in Six Minute Walk Distance (relative to base line). Data Safety Monitoring Board (DSMB) pre-specified interim analysis of safety outcomes for the first 10 patients treated in the Phase 3 trial of its investigational CardiAMP cell therapy product no significant safety concerns with the CardiAMP study results and recommended that the trial continue, as planned.



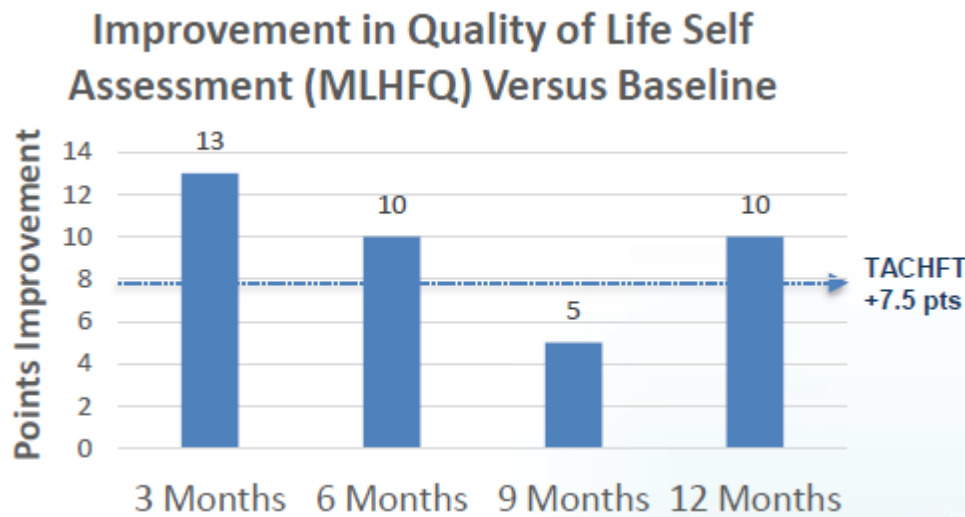
Source: BioCardia July Presentation.

Exhibit 15. Phase 3 Trial Design

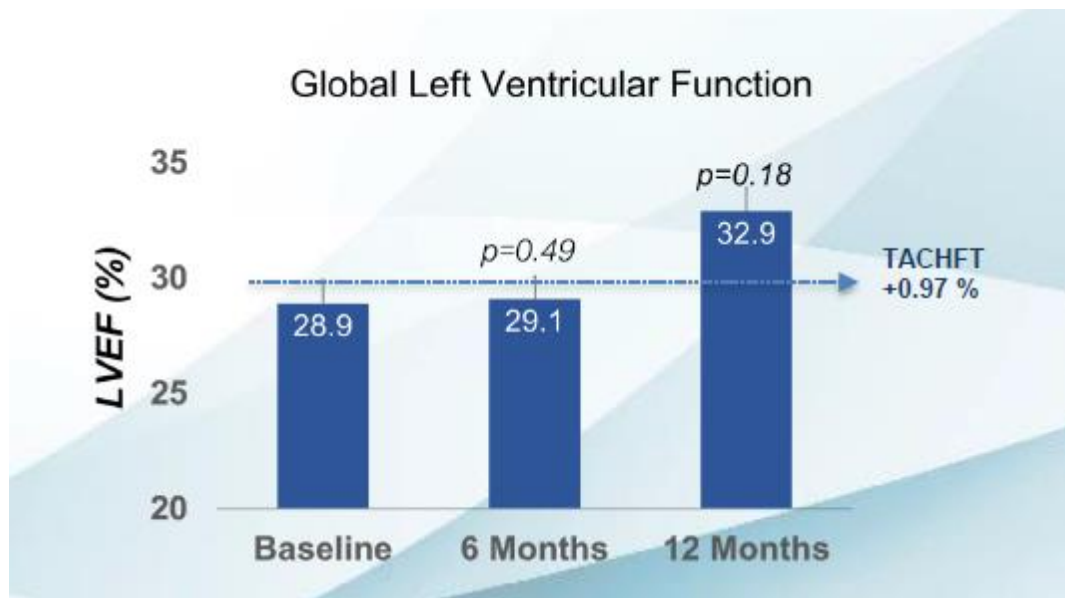


Source: BioCardia Presentation

Exhibit 16. Phase 3: QOL Measures. Results from CardiAMP-HF Study Roll-In Phase: 12-month follow-up results compared to baseline (shown as mean \pm sem). N=10 for baseline, 3 months, and 6 months; N=9 for 9 months where one patient was hospitalized, N = 10 for 12 months. Results compared to improvements in Phase 2 TAC-HFT Study.



Source: BioCardia July Presentation.



Source: BioCardia July Presentation.

Product Modeling Assumptions

1. We base our market share estimates for BioCardia's therapies on multiple assumptions around the product attributes associated with product delivery and outcomes. Given the blockbuster size of the U.S. and EU HF markets we apply a 70% risk reduction to the net revenues, suggesting on success there is a lot of upside in our estimates.
2. We assume CardiAMP and CardiALLO will initially launch at \$50,000 per operation. Our projected market share grows over the six-year launch cycle, with CardiAMP consuming up to 25% of the total market in the year 2028 and CardiALLO achieves a 15% share of the total market by the year 2030.
3. Based on BioCardia's estimation of completing enrollment of the pivotal Phase 3 trial of BCDA-01 in 2H20, we assume standard FDA review time of 10 months with the launch in 1Q22. We expect BCDA-02 to be a fast follower with approval and launch a year after BCDA-01, in 1Q23. To adjust for the risk of approval, we apply a 70% risk cut to our CardiAMP revenue model.
4. We expect that BCDA-03 (CardiALLO) could reach the market by 2027, however, for conservatism, we apply a therapeutic risk cut of 70% in our product model. This suggests that clinical progress could make our numbers too conservative.

Exhibit 17. Market Models:

BCDA-01 Heart Failure												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	5,000,000	5,005,000	5,010,005	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	500,000	500,500	501,001	501,502	502,003	502,505	503,008	503,511	504,014	504,518	505,023	505,528
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	1.0%	3.0%	6.0%	7.0%	8.0%	10.0%	14.0%	15.0%
Number of Patients Procedures	0	0	0	0	5,020	15,075	30,180	35,246	40,321	50,452	70,703	75,829
Cost of Therapy	\$ 20,040	\$ 20,040	\$ 20,080	\$ 20,120	\$ 20,160	\$ 20,201	\$ 20,241	\$ 20,282	\$ 20,322	\$ 20,363	\$ 20,404	\$ 20,444
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ 30	\$ 91	\$ 183	\$ 214	\$ 246	\$ 308	\$ 433	\$ 465
BCDA-01 Heart Failure												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	9,000,000	9,009,000	9,018,009	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	900,000	900,900	901,801	902,703	903,605	904,509	905,414	906,319	907,225	908,132	909,041	909,950
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.0%	3.0%	5.0%	10.0%	12.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	0	9,054	27,190	45,361	90,613	109,085	136,492
Cost of Therapy	\$ 30,000	\$ 30,060	\$ 30,120	\$ 30,180	\$ 30,241	\$ 30,301	\$ 30,362	\$ 30,423	\$ 30,483	\$ 30,544	\$ 30,605	\$ 30,667
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 82	\$ 248	\$ 415	\$ 832	\$ 1,002	\$ 1,256
BCDA-02 Heart Failure												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	5,000,000	5,075,000	5,151,125	5,228,392	5,306,818	5,386,420	5,467,216	5,549,225	5,632,463	5,716,950	5,802,704	5,889,745
Market Size Growth (Annual)	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Candidates (Chronic Myocardial Ischemia) for Therapy	200,000	203,000	206,045	209,136	212,273	215,457	218,689	221,969	225,299	228,678	232,108	235,590
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	25.0%	25.0%
Number of Patients Procedures	0	0	0	0	4,245	10,773	21,869	33,295	45,060	57,169	58,027	58,897
Cost of Therapy	\$ 20,040	\$ 20,040	\$ 20,080	\$ 20,120	\$ 20,160	\$ 20,201	\$ 20,241	\$ 20,282	\$ 20,322	\$ 20,363	\$ 20,404	\$ 20,444
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ 26	\$ 65	\$ 133	\$ 203	\$ 275	\$ 349	\$ 355	\$ 361
BCDA-02 Heart Failure												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	9,000,000	9,072,000	9,144,576	9,217,733	9,291,474	9,365,806	9,440,733	9,516,259	9,592,389	9,669,128	9,746,481	9,824,453
Market Size Growth (Annual)	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
Candidates (Chronic Myocardial Ischemia) for Therapy	495,000	498,960	502,952	506,975	511,031	515,119	519,240	523,394	527,581	531,802	536,056	540,345
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	2.0%	10.0%	15.0%	20.0%	20.0%	20.0%
Number of Patients Procedures	0	0	0	0	0	0	10,385	31,404	52,758	79,770	107,211	108,069
Cost of Therapy	\$ 30,000	\$ 30,060	\$ 30,120	\$ 30,180	\$ 30,241	\$ 30,301	\$ 30,362	\$ 30,423	\$ 30,483	\$ 30,544	\$ 30,605	\$ 30,667
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 95	\$ 287	\$ 482	\$ 731	\$ 984	\$ 994
BCDA-03 Heart Failure												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	5,000,000	5,005,000	5,010,005	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	150,000	150,150	150,300	150,450	150,601	150,752	150,902	151,053	151,204	151,355	151,507	151,658
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	0	0	0	3,024	7,568	15,151	22,749
Cost of Therapy	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 22,500	\$ 22,545	\$ 22,590	\$ 22,635
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 20	\$ 51	\$ 103	\$ 154
BCDA-03 Heart Failure												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	9,000,000	9,009,000	9,018,009	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	270,000	270,270	270,540	270,811	271,082	271,353	271,624	271,896	272,168	272,440	272,712	272,985
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	0	0	0	5,443	13,622	27,271	40,948
Cost of Therapy	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 29,500	\$ 29,559	\$ 29,618	\$ 29,677
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 48	\$ 121	\$ 242	\$ 365

Source: Dawson James Estimates

Exhibit 18. Comparables. The attached chart reviews some of the comparable regenerative medicine-based companies. We believe notable mentions for Blue Rock Therapeutics and Sana Biotechnology. Blue Rock was acquired in August 2019 by Bayer for \$1 billion. What's important is that Blue Rock is developing a universal pluripotent stem cells into authentic, functional cells that can be used as allogeneic cellular therapies to treat a broad array of diseases. Bayer announced the acquisition of their remaining stake for approximately \$240 million in cash to be paid upfront at closing and an additional \$360 million payable upon achievement of pre-defined development milestones. With Bayer currently holding 40.8% stake, the investment corresponds to a total company value of Blue Rock Therapeutics of approximately \$1 billion. Sana was founded by former executives of June and includes Steve Harr MD and a former biotechnology analyst and Hans Bishop and has been backed by ARCH Ventures and F-Prime Capital.

Company Name	Ticker	Share Price	Market Cap (\$MM)	Cash (\$MM)	Enterprise Value (\$MM)	Last QTR's Burn Rate	QTR's of Cash Remaining	R&D (\$MM)	SG&A (\$MM)	Shares Outstanding (MM)
Athersys	ATHX	\$1.24	\$194	\$40	\$149	(\$12)		\$9	\$12	157
BioCardia	BCDA	\$4.25	\$29	\$9	\$18	(\$4)		\$2	\$3	7
Mesoblast	MESO	\$9.51	\$1,025	\$104	\$999	(\$8)		\$13	\$8	107
Pluristem	PSTI	\$4.66	\$83	\$8	\$60	(\$6)		\$5	\$6	18
Vericel	VCEL	\$19.07	\$852	\$37	\$844	\$3		\$3	\$18	45
Average (s)	-X	\$7.75	\$437	\$40	\$414	(\$5)		6	9	67
BioCardia	BCDA	\$4.25	\$29.01	\$9	\$18	(\$4)		2	3	7

Source: Data is from FactSet as of 2/17/2020

Valuation. We value BioCardia based on the revenues in our product models, which are reduced by 70% rate cut or a 30% probability of success. This suggests we are leaving a lot of upside in our estimates on good data. We apply assumptions for FDA product approvals, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. Our price target is derived from an equal-weighted average of free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. For companies that are well established with mature products and revenues, we typically discount at a 10% rate, for companies in the early stages of product commercialization we typically use a higher rate, 15%. For BioCardia, we use a 30% risk rate as the company is not yet profitable. This risk rate is in addition to the therapeutic cut (70%) in our product models. The result of this methodology is a price target of \$24.00 per share.

Exhibit 19. Discounted Free Cash Flow Model

Average	\$	24
Price Target	\$	23
Year		2020

DCF Valuation Using FCF (mln):												
units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(14,571)	(14,852)	(15,595)	(27,709)	9,897	83,745	339,347	497,069	1,120,357	1,849,091	2,452,069	2,831,049
Tax Rate	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
EBIT(1-t)	(14,571)	(14,852)	(15,595)	(24,938)	8,115	66,996	257,904	377,772	851,471	1,331,346	1,716,449	1,868,492
CapEx												
Depreciation	78	-	-	-	-	-	-	-	-	-	-	-
Change in NWC												
FCF	(14,493)	(14,852)	(15,595)	(24,938)	8,115	66,996	257,904	377,772	851,471	1,331,346	1,716,449	1,868,492
PV of FCF	(6,597)	(5,200)	(4,200)	(5,167)	1,293	8,213	24,320	27,403	135,696	163,209	161,860	135,537
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	6,507,508											
Terminal Value YE2030	472,043											
NPV	1,115,007											
NPV-Debt	1,016											
Shares out (thousands)	47,884	2030E										
NPV Per Share	\$	23										

Source: Dawson James

Exhibit 20. EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 39.02
NPV	\$ 28.00

Source: Dawson James estimates.

Discount Rate and Earnings Multiple Varies, Year is Constant						
2030 EPS						
Earnings Multiple	5%	10%	15%	20%	25%	30%
0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$ -
5	\$120.00	\$75.00	\$48.00	\$32.00	\$21.00	\$ 14.00
10	\$240.00	\$150.00	\$96.00	\$63.00	\$42.00	\$ 28.00
15	\$359.00	\$226.00	\$145.00	\$95.00	\$63.00	\$ 42.00
20	\$479.00	\$301.00	\$193.00	\$126.00	\$84.00	\$ 57.00
25	\$599.00	\$376.00	\$241.00	\$158.00	\$105.00	\$ 71.00
30	\$719.00	\$451.00	\$289.00	\$189.00	\$126.00	\$ 85.00
35	\$838.00	\$527.00	\$338.00	\$221.00	\$147.00	\$ 99.00

Source: Dawson James

Exhibit 21. Sum-of-the-Parts Model

BioCardia	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
BCDA-01 CardiAMP cell therapy US	1%	30%	3	30%	\$1,550	\$5,346
NPV						\$6.10
BCDA-01 CardiAMP cell therapy US	1%	30%	3	30%	\$4,186	\$14,434
NPV						\$16.46
BCDA-02 CardiALLO cell therapy US	1%	30%	4	30%	\$1,204	\$4,152
NPV						\$3.64
BCDA-02 CardiALLO cell therapy EU	1%	30%	4	30%	\$3,314	\$11,428
NPV						\$10.03
BCDA-03 CardiALLO cell therapy US	1%	50%	5	30%	\$515	\$1,051
NPV						\$0.35
BCDA-02 CardiALLO cell therapy EU	1%	50%	5	30%	\$1,215	\$2,480
NPV						\$0.82
Net Margin						40%
MM Shrs OS (2030E)						48
Total						\$21

Source: Dawson James

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to BioCardia are as follows:

Partnership risk. The company is also expected to make agreements with partners for additional products, but there can be no assurances that the company will be able to secure favorable partnerships.

Commercial risk. There are no assurances that the company will be able to achieve significant sales, market share, or become profitable.

Clinical and regulatory risk. Lead products need to complete clinical trials. It is difficult to complete enrollment which could lead to a delay of the trial. Trials may not produce the results expected from previous research or be sufficient for regulatory approval.

Financial risk. The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and or do so, at favorable terms.

Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third parties' patents.

Exhibit 22. Income Statement

Biocardia Inc: Income Statement (\$000)																					
BCDA: YE December	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	76	62	1	78	300	72	76	82	85	315	331									
Collaboration agreement revenue	343	140	24	193	25	382	92	96	104	108	401	421									
BCDA-01 CardiaAMP Cell Therapy revenues US						0					0	0	60,542	151,809	304,530	458,166	612,723	614,562	770,509	772,822	775,142
BCDA-01 CardiaAMP Cell Therapy revenues EU													0	0	0	164,940	496,305	829,659	1,248,224	1,669,295	1,674,306
BCDA-02 CardiaAMP Cell Therapy revenues US														25,677	65,286	132,796	202,586	274,714	349,241	355,188	361,237
BCDA-02 CardiaAMP Cell Therapy revenues EU														-	-	94,590	28,661	482,474	730,959	984,374	994,234
BCDA-03 CardALLO Cell Therapy revenues US																	-	20,413	51,185	102,677	154,477
BCDA-03 CardALLO Cell Therapy revenues EU	-																-	48,174	120,796	242,317	364,566
Total Product Sales	625	216	86	194	103	599	165	172	186	193	716	752	60,542	177,486	369,816	850,492	1,340,275	2,269,995	3,270,913	4,126,672	4,323,962
Product Sales & Royalties & Milestones	-	-	-	-	-	-	-	-	-	-	-	-	60,542	177,486	369,816	590,962	815,308	957,862	1,291,730	1,473,003	1,655,422
Expenses																					
Cost of goods sold	517	106	191	24	141	543	49	52	56	58	215	226	18,163	44,372	92,454	204,118	308,263	499,399	686,892	825,334	864,792
							30%	30%	30%	30%	30%	30%	30%	25%	25%	24%	23%	22%	21%	20%	20%
Research and Development	8,453	2,166	2,219	2,007	2,308	8,876	2,143	2,237	2,330	2,423	9,319	9,785	10,275	10,788	11,328	11,894	12,489	13,113	13,769	14,457	15,180
Selling, general and administrative	5,757	1,631	1,438	1,390	1,572	6,045	1,460	1,523	1,587	1,650	6,347	6,664	18,000	22,000	23,100	24,255	25,468	26,741	28,078	29,482	30,956
Total expenses	14,727	3,903	3,848	3,421	4,020	15,192	3,653	3,812	3,972	4,131	15,568	16,346	45,872	76,504	126,193	239,544	345,461	538,456	727,902	868,395	910,006
Operating income (Loss)	(14,102)	(3,687)	(3,762)	(3,227)	(3,917)	(14,593)	(3,488)	(3,640)	(3,786)	(3,938)	(14,852)	(15,595)	14,670	100,982	243,623	610,948	994,814	1,731,539	2,543,011	3,258,277	3,413,956
Interest expense																					
Interest Income	118	23	23	69	23	23															
Other expense	(3)	(1)	(1)	(634)	(1)	(1)															
Total other income	115	22	(1)	(634)	(1)	(1)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(3,665)	(3,740)	(3,792)	(3,895)	(14,571)	(3,488)	(3,640)	(3,786)	(3,938)	(14,852)	(15,595)	14,670	100,982	243,623	610,948	994,814	1,731,539	2,543,011	3,258,277	3,413,956
Income Tax Benefit (Provision)		-	-	-	-	-	-	-	-	-	-	-	1,467	18,177	48,725	146,628	238,755	415,569	712,043	977,483	1,160,745
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
GAAP Net Income (loss)	(13,987)	(3,665)	(3,740)	(3,792)	(3,895)	(14,571)	(3,488)	(3,640)	(3,786)	(3,938)	(14,852)	(15,595)	13,203	82,805	194,898	464,321	756,059	1,315,969	1,830,968	2,280,794	2,253,211
Deemed Dividend on Preferred Stock																					
GAAP-EPS	(0.37)	(0.08)	(0.77)	(0.63)	(0.46)	(0.92)	(0.41)	(0.23)	(0.24)	(0.25)	(1.08)	(0.64)	0.51	3.20	7.51	17.83	28.91	50.12	69.46	86.17	84.79
GAAP EPS (dil)	(0.37)	(0.08)	(0.77)	(0.63)	(0.65)	(0.96)	(0.32)	(0.14)	(0.15)	(0.15)	(0.67)	(0.36)	0.28	1.78	4.17	9.89	16.04	27.81	38.54	47.82	47.06
Weighted shares basic	38,285	43,629	4,848	6,031	8,537	15,761	8,545	15,554	15,569	15,585	13,813	24,385	25,737	25,840	25,943	26,047	26,151	26,256	26,361	26,467	26,573
Weighted shares dil	38,285	43,629	4,848	6,031	6,037	15,136	11,043	26,054	26,080	26,106	22,321	43,694	46,376	46,562	46,749	46,936	47,124	47,313	47,502	47,693	47,884

Source: Dawson James estimates.

Companies mentioned in this report:

Bayer (BAYRY): Not Covered

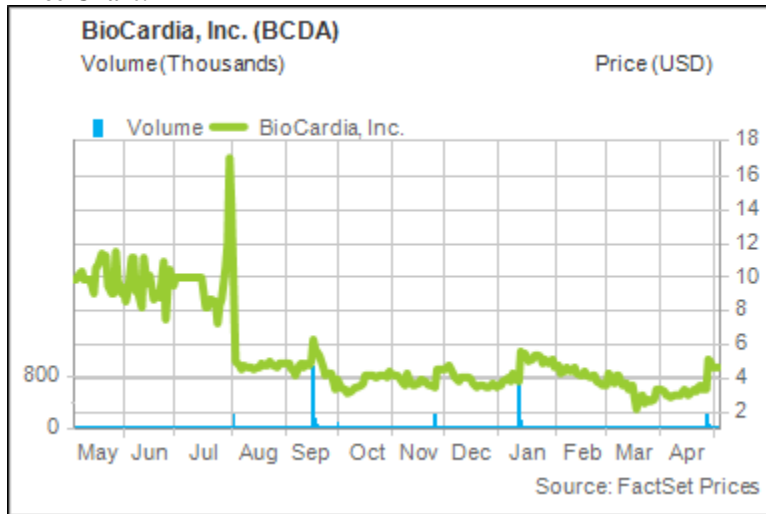
Blue Rock Therapeutics (acquired by Bayer)

June (acquired by Celgene – CELG, Not Covered).

Sana Biotech (Private)

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

Initiated – Buy – September 17, 2019 – Price Target \$24.00

Update – Buy – November 20, 2019 – Price Target \$24.00

Update – Buy – February 18, 2020 – Price Target \$24.00

Update – Buy – May 5, 2020 – Price Target \$24.00

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	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	92%	3	14%
Market Perform (Neutral)	2	8%	1	50%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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